



09/470603

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Docket No.: 20718/1204135-US8  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Letters Patent of:  
David J. Bova

Patent No.: 7,011,848

Issued: March 14, 2006

For: NICOTINIC ACID COMPOSITIONS FOR  
TREATING HYPERLIPIDEMIA AND  
RELATED METHODS THEREFOR

**Certificate**  
SEP 28 2006  
**of Correction**

**REQUEST FOR CERTIFICATE OF CORRECTION  
PURSUANT TO 37 CFR 1.323**

Attention: Certificate of Correction Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Upon reviewing the above-identified patent, Patentee noted typographical errors which should be corrected.

**In the Specification:**

At column 2, line 34, please delete the phrase "18 or 78 percent" and insert the phrase --12 or 52 percent --.

At column 15, line 34, please delete the phrase "had 18 of 23, or 78 percent" and insert the phrase --had 12 of 23, or 52 percent--.

OCT - 2 2006

09/25/06 10:00 AM 09/25/06 10:00 AM  
09/25/06 10:00 AM 09/25/06 10:00 AM

At column 14, line 44 to column 15, line 30, please replace Table VIII with the following corrected replacement table:

**TABLE VIII**  
**A Comparison of Changes in Liver Function Tests**

	DOSE							
	0	500	1000	1500	2000	2500	3000	TOTAL
<b>McKenney SR<sup>b</sup>Niacin</b>								
AST	23.8	27.9	40.4	36.6	56.5	na	97.0	
%	--	117	170	154	237	na	408	
<b>Invention Dosage<sup>c</sup></b>								
AST	24.3	na	23.7	27.5	26.6	27.6	27.8	
%	--	na	98	113	109	114	114	
<b>McKenney SR Niacin</b>								
AST	25.6	29.5	36.3	39.0	59.1	na	100.0	
%	--	115	142	152	231	na	391	
<b>Invention Dosage</b>								
ALT	21.4	na	18.7	22.6	21.3	22.4	21.8	
%	--	na	87	106	100	105	102	
<b>McKenney SR Niacin</b>								
ALK	95	95	106	105	136	na	135	
%	--	100	112	111	143	na	142	
<b>Invention Dosage</b>								
ALK	74.7	na	73.9	76.1	73.4	76.7	78.0	
%	--	na	99	102	98	103	104	
<b>McKenney SR Niacin</b>								
Drop	--	0	1	2	4	na	5	12
n	--	--	--	--	--	--	--	23
%	--	0	4	9	17	na	22	52
<b>Invention Dosage</b>								
Drop	--	--	0	0	0	0	0	0
n	--	--	26	67	97	35	15	240
%	--	--	0	0	0	0	0	0
1 year	--	--	15	47	77	31	15	184
1 year	--	--	58	69	79	89	100	77

Dosed twice-per-day as described in "A Comparison of the Efficacy and Toxic Effects of Sustained - vs. Immediate - Release Niacin in Hypercholesterolemic Patients" by McKenney et al., *Journal of the American Medical Association*, March 2, 1994; Vol. 271, No. 9, pages 672-677.

<sup>b</sup> SR is "sustained release"

<sup>c</sup> Dosed once-per-day at night

20718-2 2001

**Remarks:**

The errors were found in the application as filed by applicant. The errors now sought to be corrected are inadvertent typographical errors, the correction of which does not involve new matter or require reexamination.

Our check in the amount of \$100.00 covering the fee set forth in 37 CFR 1.20(a) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Transmitted herewith is a proposed Certificate of Correction effecting such amendment. Patentee respectfully solicits the granting of the requested Certificate of Correction.

Dated: September 21, 2006

Respectfully submitted,

By: 

Paul M. Zagar, M.D.

Reg. No. 52,392

DARBY & DARBY P.C.

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Attorneys/Agents For Applicant

**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

PATENT NO. : 7,011,848  
APPLICATION NO. : 09/470,603  
ISSUE DATE : March 14, 2006  
INVENTOR(S) : David J. Bova

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 2, line 34, please delete the phrase "18 or 78 percent" and insert the phrase --12 or 52 percent --.

At column 15, line 34, please delete the phrase "had 18 of 23, or 78 percent" and insert the phrase --had 12 of 23, or 52 percent--.

OCT - 2 2006

MAILING ADDRESS OF SENDER:  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257

Patent No.: 7,011,848

Page 1 of 2

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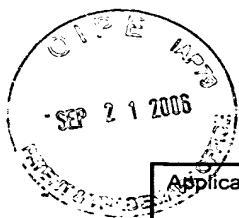
<sup>b</sup> SR is "sustained release"

<sup>c</sup> Dosed once-per-day at night

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Patent No.: 7,011,848

Page 2 of 2



Application No. (if known): 09/470,603

Attorney Docket No.: 20718/1204135-US8

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. **EV834732721-U** in an envelope addressed to:

Attention: Certificate of Correction Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on September 21, 2006  
Date

  
Signature

Lillian Garcia  
Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Fee Transmittal (1 page);  
Request for Certificate of Correction (Fee Required) (3 pages);  
Certificate of Correction (2 pages);  
Check No. 12569 in the amount of \$100.00; and  
Return postcard.



PTO/SB/17 (07-06)

Approved for use through 01/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

<b>Effective on 12/08/2004.</b> <b>Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).</b> <b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		<b>Complete if Known</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number	Patent#: 7,011,848
<b>TOTAL AMOUNT OF PAYMENT</b> (\$) 100.00		Filing Date	Issued: March 14, 2006
		First Named Inventor	David J. Bova
		Examiner Name	Robert M. Joynes
		Art Unit	N/A
		Attorney Docket No.	20718/1204135-US8

<b>METHOD OF PAYMENT</b> (check all that apply)	
<input checked="" type="checkbox"/> Check	<input type="checkbox"/> Credit Card
<input type="checkbox"/> Money Order	<input type="checkbox"/> None
<input type="checkbox"/> Other (please identify): _____	
<input type="checkbox"/> Deposit Account	Deposit Account Number: 04-0100
Deposit Account Name: Darby & Darby P.C.	
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)	
<input type="checkbox"/> Charge fee(s) indicated below	<input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee
<input type="checkbox"/> Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17	<input checked="" type="checkbox"/> Credit any overpayments

<b>FEE CALCULATION</b>							
<b>1. BASIC FILING, SEARCH, AND EXAMINATION FEES</b>							
	<b>FILING FEES</b>		<b>SEARCH FEES</b>		<b>EXAMINATION FEES</b>		
		<b>Small Entity</b>		<b>Small Entity</b>		<b>Small Entity</b>	
<b>Application Type</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fees Paid (\$)</b>
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	
<b>2. EXCESS CLAIM FEES</b>							
<b>Fee Description</b>						<b>Small Entity</b>	<b>Fee (\$)</b>
Each claim over 20 (including Reissues)						50	25
Each independent claim over 3 (including Reissues)						200	100
Multiple dependent claims						360	180
<b>Total Claims</b>		<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>	<b>Multiple Dependent Claims</b>		
- =		x	=		<b>Fee (\$)</b>		<b>Fee Paid (\$)</b>
HP = highest number of total claims paid for, if greater than 20.							
<b>Indep. Claims</b>		<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>			
- =		x	=				
HP = highest number of independent claims paid for, if greater than 3.							
<b>3. APPLICATION SIZE FEE</b>							
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
<b>Total Sheets</b>		<b>Extra Sheets</b>	<b>Number of each additional 50 or fraction thereof</b>		<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>	
- 100 =		/50	(round up to a whole number) x		=		
<b>4. OTHER FEE(S)</b>							
Non-English Specification, \$130 fee (no small entity discount)						<b>Fees Paid (\$)</b>	
Other (e.g., late filing surcharge): 1811 Certificate of correction						100.00	

<b>SUBMITTED BY</b>			
Signature		Registration No. (Attorney/Agent)	52,392
Name (Print/Type)	Paul M. Zagar	Telephone	(212) 527-7700
		Date	September 21, 2006